

## PATENT APPLICATION

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8-3-01  
Date

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Adler, David A. et al.  
Application No. :  
Filed : March 17, 2000  
For : SECRETED SALIVARY ZSIG63 POLYPEPTIDE

Examiner :

Art Unit :

Docket No.: 98-71D1

Date : August 3, 2001

Box Non-Fee Amendment

Commissioner for Patents

Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Dear Sir:

Applicants respectfully request consideration of the following preliminary amendments. Please amend the subject application as follows:

### IN THE CLAIMS

Please cancel claim 10 without prejudice to the prosecution thereof in a subsequent application.

Please amend the following claims:

9. (Amended) A fusion protein produced by a method comprising:

culturing a host cell into which has been introduced a vector comprising the following operably linked elements:

(a) a transcriptional promoter;

(b) a DNA construct encoding a fusion protein, the DNA construct comprising:

a first DNA segment encoding a polypeptide selected from the group consisting of:

(i) the amino acid sequence of SEQ ID NO: 2 from residue number 1 (Met) to residue number 15 (Ala);

(ii) the amino acid sequence of SEQ ID NO:2 from residue number 16 (Arg) to residue number 219 (Gln); and

at least one other DNA segment encoding an additional polypeptide, wherein the first and other DNA segments are connected in-frame; and encode the fusion protein; and

(c) a transcriptional terminator; and

recovering the protein encoded by the DNA segment.

11. (Amended) An isolated polypeptide comprising a sequence of amino acid residues selected from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln).

19. An isolated polypeptide according to claim 11, wherein the polypeptide consists of a sequence of amino acid residues selected from the group consisting of:

(d) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln).

20. An isolated polypeptide according to claim 11, wherein the polypeptide encoded by the polynucleotide has activity as measured by activation of transcription of a reporter gene, anti-microbial activity, or wherein the polypeptide encoded by the polynucleotide further binds to an antibody,

wherein the antibody is raised to a polypeptide comprising a sequence of amino acids from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);

(d) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln); and

wherein the binding of the antibody to the isolated polypeptide is measured by a biological or biochemical assay including radioimmunoassay, radioimmuno-precipitation, Western blot, or enzyme-linked immunosorbent assay.

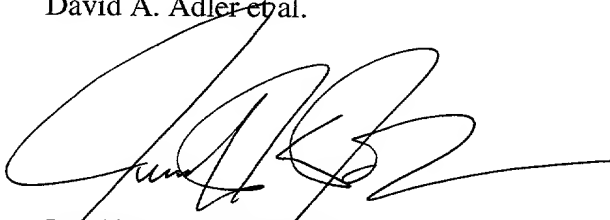
#### **REMARKS**

Claims 9-11 are pending in the instant application. Claims 1-8, 12, and 13-18 have been withdrawn from consideration. Claim 9 was re-written in independent format and to provide clarity to the claim. Claim 10 was canceled for business purposes, and to expedite prosecution. Claim 11 was re-written in independent format, to provide clarity to the claim, and so that it would not depend from a cancelled claim. New claims 19, and 20 were added as dependent claims to provide claims of various scope encompassed by the invention. Support for the new claims is provided throughout the specification and sequence listing. The instant claims are drawn to polypeptides and related inventions. A marked-up version of the changes made to the claims by the current preliminary amendment, "Explanation Of Amendments With Markings," is provided. An Appendix with the claim set including amended claims is provided for the Examiner's convenience, and shall not be construed as submission of a re-presented claim set under 37 CFR §1.121. No new matter was added by these amendments.

Early reconsideration and allowance of the pending claims is respectfully requested. If the Patent Examiner believes that a telephone interview would expedite prosecution of this patent application, please call the undersigned at (206) 442-6676.

Respectfully Submitted,

David A. Adler et al.

A handwritten signature in black ink, appearing to read 'Jennifer K. Johnson', written over the printed name.

Jennifer K. Johnson, J.D.

Registration No. 43,696

Enclosures:

Amendment Fee Transmittal (in duplicate)

Explanation Of Amendments With Markings To Show Changes (3 pages)

Appendix (3 pages)

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## EXPLANATION OF AMENDMENTS WITH MARKINGS TO SHOW CHANGES MADE

### IN THE CLAIMS:

Please cancel claim 10 without prejudice to the prosecution thereof in a subsequent application:

~~10. An isolated zsig63 polypeptide comprising a sequence of amino acid residues that is at least 90% identical to an amino acid sequence selected from the group consisting of:—~~

~~(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);—~~

~~(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);—~~

~~(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);—~~

~~(d) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and~~

~~(e) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 1 (Met) to amino acid number 219 (Gln).~~

Please amend the following claims:

9. (Amended) A fusion protein produced by a method comprising:

culturing a host cell into which has been introduced a vector comprising the following operably linked elements:

(a) a transcriptional promoter;

(b) a DNA construct encoding a fusion protein, ~~according to claim 8~~ the DNA construct comprising:

a first DNA segment encoding a polypeptide selected from the group consisting of:

(i) the amino acid sequence of SEQ ID NO: 2 from residue number 1 (Met) to residue number 15 (Ala);

(ii) the amino acid sequence of SEQ ID NO:2 from residue number 16 (Arg) to residue number 219 (Gln); and

at least one other DNA segment encoding an additional polypeptide,  
wherein the first and other DNA segments are connected in-frame; and  
encode the fusion protein; and

(c) a transcriptional terminator; and

recovering the protein encoded by the DNA segment.

11. (Amended) An isolated ~~zsig63~~ polypeptide comprising according to claim 10, wherein the polypeptide comprises a sequence of amino acid residues selected from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);

(d) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln).

Please add the following claims:

-- 19. An isolated polypeptide according to claim 11, wherein the polypeptide consists of a sequence of amino acid residues selected from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);

(d) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln).

20. An isolated polypeptide according to claim 11, wherein the polypeptide encoded by the polynucleotide has activity as measured by activation of transcription of a reporter gene, anti-microbial activity, or wherein the polypeptide encoded by the polynucleotide further binds to an antibody,

wherein the antibody is raised to a polypeptide comprising a sequence of amino acids from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);

(d) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln); and

wherein the binding of the antibody to the isolated polypeptide is measured by a biological or biochemical assay including radioimmunoassay, radioimmuno-precipitation, Western blot, or enzyme-linked immunosorbent assay. --



### Claim Set with Amended Claims

What is claimed is:

9. A fusion protein produced by a method comprising:

culturing a host cell into which has been introduced a vector comprising the following operably linked elements:

(a) a transcriptional promoter;

(b) a DNA construct encoding a fusion protein, the DNA construct comprising:

a first DNA segment encoding a polypeptide selected from the group consisting

of:

(i) the amino acid sequence of SEQ ID NO: 2 from residue number 1 (Met) to residue number 15 (Ala);

(ii) the amino acid sequence of SEQ ID NO:2 from residue number 16 (Arg) to residue number 219 (Gln); and

at least one other DNA segment encoding an additional polypeptide,  
wherein the first and other DNA segments are connected in-frame; and  
encode the fusion protein; and

(c) a transcriptional terminator; and

recovering the protein encoded by the DNA segment.

11. An isolated polypeptide comprising a sequence of amino acid residues selected from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln).

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(c) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 127 (Pro) to amino acid number 219 (Gln);

(d) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 16 (Arg) to amino acid number 219 (Gln); and

(e) the amino acid sequence as shown in SEQ ID NO:2 from amino acid number 1 (Met) to amino acid number 219 (Gln).

20. An isolated polypeptide according to claim 11, wherein the polypeptide encoded by the polynucleotide has activity as measured by activation of transcription of a reporter gene, anti-microbial activity, or wherein the polypeptide encoded by the polynucleotide further binds to an antibody,

wherein the antibody is raised to a polypeptide comprising a sequence of amino acids from the group consisting of:

(a) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 16 (Arg) to amino acid number 37 (Ser);

(b) the amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 38 (Leu) to amino acid number 126 (Ala);

wherein the binding of the antibody to the isolated polypeptide is measured by a biological or biochemical assay including radioimmunoassay, radioimmuno-precipitation, Western blot, or enzyme-linked immunosorbent assay.